UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,545	12/31/2003	Jon D. Kaiser	069738-0011	5578

41552 7590 09/26/2007

MCDERMOTT, WILL & EMERY
4370 LA JOLLA VILLAGE DRIVE, SUITE 700
SAN DIEGO, CA 92122

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
09/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,545	KAISER, JON D.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-66 have been cancelled. Claims 1-27 are under examination.

The Examiner has carefully considered the 1.132 Declaration by Dr. Kaiser. In the 1.132 declaration, Applicant asserts that this is the only formulation known to enhance the immune response in people infected with HIV (6) and it isn't simply an obvious reorganization of the ingredients taught in the art (8). The success with patients with the formulation is noted (11). However, claim language is controlling and claim 1 is not drawn to ***the specific synergistic combination*** that works so well in enhancing the immune system of people infected with HIV that took years for Dr. Kaiser to develop. As Applicant stated, it isn't any choice of compounds that work together to produce this effect. Therefore, the claims are not commensurate in scope with the subject matter that works in enhancing the immune system of people infected with HIV.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Barker et al. WO 00/76492.

Barker et al. disclose in claim 1 a combination of nutrients comprising:

Vitamin E	50-500 IU

Vitamin C	60-500 mg
Selenium	20-300 mcg
N-acetyl-l-cysteine	500-2000 mg
Curcumin	5-50 mg
Mixed polyphenols	500-1500 mg green tea extract
Mixed carotenoids	500-2000 mg mixed vegetable extract.

Thus, Barker clearly discloses a composition with a vitamin antioxidant, a mineral antioxidant and 3 high potency antioxidants (carotenoids, polyphenols and N-acetyl-l-cysteine) in a highly saturable amount thus anticipating instant claims 1, 4, 5, 6 and 9. Barker et al. teach the inclusion of one or more additional antioxidant agents beyond the antioxidant active components specified (page 11, lines 3-6).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, (for augmenting immune strength or physiological detoxification) however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Response to arguments:

Applicant asserts that the reference teaches carotenoids and polyphenols which include beta-carotene and flavonoids and therefore do not meet applicant's definition of high potency antioxidant. The Examiner cannot agree. Carotenoids also embrace lutein and astaxanthin which

are not defined as applicant as vitamin anti-oxidants and are therefore high potency antioxidants. Polyphenols also embrace curcuminoids which are not flavonoids and therefore meet the limitations of Applicants definitions. The rejection stands.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-27 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosbab (US 2001/0031744).

Kosbab teaches therapeutic compositions and provides an exemplary formulation dosage comprising at least one vitamin antioxidant, at least one mineral antioxidant and at least three high potency antioxidants: 1000 mg vitamin C; 714 mg vitamin E; 4.88 mg vitamin B6; 5000 IU vitamin A; 30 mg zinc; 20 mg alpha lipoic acid; 200 mg N-acetyl-cysteine; 50 mg acetyl L-carnitine (Page 21, Table 4). Kosbab teaches preferred dosage ranges for exemplary formula components: 10-5000 mg vitamin C; 5-800 mg vitamin E; 0.001-200 mg vitamin B6; 1000-25000 IU vitamin A; 1-2000 mg quercitin (bioflavonoids); 10-3000 mg zinc; 0.001-50 mg selenium; 5-1000 mg alpha lipoic acid; 5-3000 mg N-acetyl-cysteine; and 10-3000 mg acetyl L-carnitine (Page 21, Table 3). Kosbab does not add fillers, binders or lubricants so the composition is substantially pure. The weight range of high potency antioxidants that can be in

the composition of Kosbab encompasses the amount as disclosed in the instant specification in Figure 1:

Three colored capsules contain:	
Alpha Lipoic Acid	200 mg
Acetyl L-Carnitine	500 mg
N-Acetyl Cysteine	600 mg

Figure 1

1. Kosbab does not expressly disclose a nutrient composition comprising highly saturable amounts of at least three high potency antioxidants.

2. Kosbab does not expressly disclose a nutrient composition with at least three vitamin antioxidants, at least two mineral antioxidants and at least 3 high potency antioxidants.

3. Kosbab does not expressly disclose a nutrient composition for augmenting immune strength or physiological detoxification comprising an optimal combination of a substantially pure and an effective amount of vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Kosbab to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Kosbab provides the preferred dosage ranges of formula components such that one of ordinary skill in the art could reduce to practice the instant invention by: 1) adding highly saturable amounts of at least 3 high potency antioxidants; 2) adding selenium as another mineral antioxidant and produce

a formula comprising 3) vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, (for augmenting immune strength or physiological detoxification) however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Response to arguments:

Applicant asserts that there is no teaching, suggestion or motivation to arrive at the instant combination of three high potency antioxidants in highly saturable amounts. The Examiner cannot agree. As discussed above, the art teaches the combination of these elements. The comprising claim language of instant claim 1 does not exclude other elements. **The claim language is not commensurate in scope with the evidence of unexpected results.** Applicant's arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 1-27 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek (US 6,103,756) in view of Ames et al. (US 5,916,912) and Kosbab (US 2001/0031744).

The references of Gorsek and Kosbab are discussed above and those discussions are hereby incorporated by reference.

Gorsek teaches a serving size contained in 6 capsules that comprising: 150 mg alpha lipoic acid; 200 mg N-acetyl-cysteine; 10 mg glutathione; 1.5 g vitamin C; 500 IU vitamin E; 17,500 IU vitamin A; 800 mcg folic acid; 50 mg vitamin B6; 25 mg zinc; 200 mcg selenium and 450 mg of bioflavonoids from 3 sources. Gorsek teaches that one skilled in the art can easily modify or change the formulation within the specific description to provide a unique product (Column 2, lines 25-27). The Examiner interprets this to mean that one of ordinary skill in the art can add or subtract to the amount of each ingredient.

1. Gorsek does not expressly disclose a nutrient composition comprising acetyl L-carnitine.

2. Gorsek does not expressly disclose a nutrient composition for augmenting immune strength or physiological detoxification comprising an optimal combination of a substantially pure and an effective amount of vitamin C, bioflavonoid complex, vitamin E, zinc, selenium, alpha lipoic acid, acetyl L-carnitine and N-acetyl-cysteine. The reference of Gorsek is lacking acetyl L-carnitine.

Ames et al. teaches a formulation comprising at least one antioxidant (250 mg of: glutathione, N-acetyl cysteine and lipoic acid) and 250 mg of acetyl L-carnitine (Claims 1, 6, 8

and 10, for example). Ames et al. disclose the beneficial effect of administering the combination on restoring mitochondrial function in older animals (Column 1, lines 40-47).

Kosbab teaches the amount of antioxidants to use in the composition (Page 21, Table 3).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Gorsek with a highly saturable amount of acetyl L-carnitine, as suggested by Ames et al. and Kosbab, for the purpose of reversing the indicia of aging, as taught by Ames et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because restoration of youth is a desirable health benefit as well as an excellent marketing feature to the composition.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, (for augmenting immune strength or physiological detoxification) however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural

difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Response to arguments:

Applicant asserts that there is no teaching, suggestion or motivation to arrive at the instant combination of three high potency antioxidants in highly saturable amounts. The Examiner cannot agree. As discussed above, the art teaches the combination of these elements. The comprising claim language of instant claim 1 does not exclude other elements. **The claim language is not commensurate in scope with the evidence of unexpected results.** Applicant's arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al. WO 00/76492 in view of Ames et al. (US 5,916,912) and Kosbab (US 2001/0031744).

Applicant claims a nutrient composition for augmenting immune strength or physiological detoxification.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The references of Barker et al. and Kosbab et al. and Ames et al. are discussed in detail above and those discussions are hereby incorporated by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Barker et al. do not expressly teach a composition comprising alpha lipoic acid; acetyl-L-carnitine, co-enzyme Q10, glutathione, bioflavonoid complex, vitamin B6, beta-carotene, zinc, or purity levels of 99% of the ingredients.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add alpha lipoic acid; acetyl-L-carnitine, co-enzyme Q10, glutathione, bioflavonoid complex, vitamin B6, beta-carotene, and zinc, in the amounts suggested by Kosbab et al. and Ames et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Barker teaches the addition of other active antioxidants but doesn't teach which ones and Kosbab et al. and Ames et al. cure this deficiency by provide the teachings for these additional components to add to the composition. It is the Examiner's position that one of ordinary skill in the art would choose the highest purity materials, 99%, to go into a pharmaceutical preparation. The addition of 3 vitamin antioxidants and 2 mineral antioxidants is merely a matter of routine optimization by one of ordinary skill in the art especially when Barker et al. teaches adding additional components.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that there is no teaching, suggestion or motivation to arrive at the instant combination of three high potency antioxidants in highly saturable amounts. The Examiner cannot agree. As discussed above, the art teaches the combination of these elements. The comprising claim language of instant claim 1 does not exclude other elements. **The claim language is not commensurate in scope with the evidence of unexpected results.** Applicant's arguments are not persuasive and the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

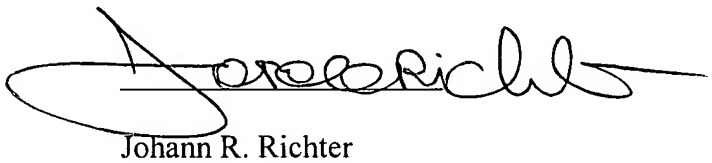
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616



Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600